

## REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-41, and 58-73 are withdrawn.

Claims 42 and 46 are currently amended.

Claims 43-45, 47-50, and 54-55, have been cancelled.

Claim 42 has been amended to recite, "wherein a deviation is significant if the absolute value of the adjusted target quantity is less than 2% of the adjusted reference quantity." This is supported in the specification in paragraphs [0048], [0096] and [0097]. Claim 42 has also been amended to remove the term "animal."

Claim 46 has been amended to remove reference to cellular extract and urine.

### **I. Claim Rejections under 35 USC §112**

A. The Examiner has rejected Claims 42, 46, 51-53, 56, and 57 under 35 USC §112, second paragraph, for being indefinite due to the term, "a significant deviation of the adjusted target quantity compared to the adjusted reference quantity is a pre-clinical or clinical indication of a specific LSD, wherein a deviation is significant if the absolute value of the deviation is greater than or equal to a standard deviation calculated by a Mann-Whitney U (MWU) test."

Applicants have amended Claim 42 to recite, "wherein a deviation is significant if the absolute value of the adjusted target quantity is less than 2% of the adjusted reference quantity." This claim is supported by the method described in paragraph [0048] of the specification, and the term "significant" is further defined in paragraph [0097] of the specification, which teaches that the

MPS I multiplex ratio data for  $\alpha$ -iduronidase to LAMP-1 was below the 2nd percentile cut-off for 16/17 plasmas and 4/4 blood spots.

Therefore, the claim clearly describes the limitations of the method, and is fully supported in the specification. Applicants believe that this will overcome the Examiner's objection.

**B.** The Examiner has rejected Claims 42, 46, 51-53, 56, and 57 under 35 USC §112, second paragraph, for being indefinite because the claims recite all biological samples or any and all target animals.

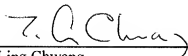
Applicants have amended Claim 42 to recite a human subject. Claim 46 has been amended to recite a sample which is blood or plasma. Therefore, the claims no longer recite all biological samples or any and all target animals, and Applicants believe the rejection is overcome.

## II. Conclusion

Applicants respectfully submit that, in light of the foregoing comments, all pending claims are in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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Date